

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARTHROCARE CORPORATION,

Plaintiff,

v.

SMITH & NEPHEW, INC.

Defendant.

C.A. No. 01-504-SLR

**SMITH & NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS RULE 50(b) MOTION
FOR JUDGMENT AS A MATTER OF LAW**

Dated: June 30, 2003

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I. NATURE AND STAGE OF THE PROCEEDINGS

For the Nature and Stage of the Proceedings, please see Smith & Nephew's Opening Brief in Support of Its Motion for a New Trial, filed concurrently.

II. SUMMARY OF THE ARGUMENT

ArthroCare failed to introduce evidence to show that Smith & Nephew itself directly infringes, contributes to the infringement by others, or actively induces infringement by others of any of the claims in suit. Since ArthroCare bears the burden of proving each of these allegations, its failure to carry these burdens requires judgment as a matter of law (JMOL) for Smith & Nephew on the following issues:

- (1) Neither Smith & Nephew's accused probes nor the use of these probes infringe the patents-in-suit under the doctrine of equivalents.
- (2) Smith & Nephew does not directly infringe the method claims of the '592 and '882 Patents.
- (3) Smith & Nephew's accused probes do not infringe the claims of the '536 patent because ArthroCare failed to prove these probes include all of the elements required by the '536 patent within an "electrosurgical system" as required by the claims.
- (4) Smith & Nephew's accused probes do not infringe the claims of the '592 patent because ArthroCare failed to prove that the accused probes satisfy the requirement that "the return electrode is not in contact with the body structure" or the requirement of "spacing a return electrode away from the body structure". Similarly, Smith & Nephew's accused probes do not infringe claim 47 of the '536 patent because ArthroCare failed to prove the return electrodes on the probes are "sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue".
- (5) Smith & Nephew's accused probes do not infringe the claims of the '882 patent because ArthroCare failed to prove that the accused probes have "an electrode terminal," "a return electrode," "an active electrode," and "an electrically conducting terminal," all of which are required because the Certificate of Correction is not valid.

(6) Non-suction models of Smith & Nephew's Saphyre products do not infringe claim 54 of the '882 patent because they do not "evacuat[e] fluid generated at the target site with a suction lumen having a distal end adjacent the electrode terminal".

(7) Smith & Nephew is not liable for contributing to the infringement of any claim of the patents-in-suit.

(8) Smith & Nephew is not liable for inducement of infringement of any claim of the patents-in-suit.

Moreover, no reasonable jury could find that Smith & Nephew did not prove—with clear and convincing evidence—that each of the asserted claims is invalid as anticipated and/or non-enabled. Entry of JMOL is therefore appropriate. Specifically:

(9) ArthroCare presented no expert testimony or any other evidence to rebut Smith & Nephew's evidence that six prior art references anticipate the asserted claims. Nor did ArthroCare dispute the prior art status of any of Smith & Nephew's invalidating art.

(10) Rather than present an answering case on validity, ArthroCare's counsel relied exclusively on an incomplete and cursory cross-examination of Smith & Nephew's expert, Dr. Taylor. Because this cross-examination fell far short of establishing any basis on which a reasonable jury could have found for ArthroCare on validity, Smith & Nephew is entitled to judgment as a matter of law. ArthroCare merely threw up a smoke screen of alleged "concessions by Dr. Taylor," and succeeded in confusing the jury. This confusion is highlighted best by the Pao '499 patent, which Smith & Nephew showed anticipated claims 46 and 56 of the '536 patent. ArthroCare's cross-examination on this point was limited to an element present only in claim 47, against which Pao *was not even asserted*. Nonetheless, the jury—apparently confused by ArthroCare's misleading cross-examination and argument—found Pao did not anticipate claims 46 and 56.

(11) Likewise, ArthroCare presented no evidence to rebut Smith & Nephew's clear and convincing evidence that the '882 patent is invalid for lack of enablement. ArthroCare

asserts that the '882 patent discloses a new phenomenon of physics called "coblation" (as assert it ArthroCare must, because otherwise the '882 patent merely describes well-known electrosurgical techniques from the prior art). But despite saying that this "coblation" phenomenon is highly dependent on very exact parameters, the specification does not describe those parameters with specificity. Thus, to the extent that the '882 is not invalid as being anticipated by the prior art, it is invalid for lack of enablement.¹

III. CONCISE STATEMENT OF FACTS

The facts related to each of the grounds upon which Smith & Nephew moves for judgment as a matter of law are addressed in each of the corresponding sections of the argument.

IV. ARGUMENT

A. Applicable Legal Standards

Entry of judgment as a matter of law (JMOL) is appropriate where "the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings." *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998). The question is not whether there is "literally no evidence" supporting the non-moving party, *Lifescan, Inc. v. Home Diagnostics, Inc.*, 103 F. Supp. 2d 345, 350-51 (D. Del. 2000), but whether the evidence *reasonably* supports the jury's verdict. *Gomez v. Alleghany Health Servs. Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995).

District courts grant JMOL if, upon the record before the jury, reasonable jurors could not have reached that verdict. Fed. R. Civ. P. 50; *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984). In deciding whether to grant JMOL on any issue after a jury has returned a verdict, the court determines whether substantial evidence exists in the record to support the jury's verdict when the correct legal standard is applied. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975 (Fed.

¹ In addition to the specific grounds of JMOL discussed in detail herein, Smith & Nephew also renews and reserves all of its arguments with respect to claim construction as set forth in its claim

Cir. 1995), *aff'd*, 517 U.S. 370 (1996). Substantial evidence is the quantum of evidence that reasonable jurors would accept as adequate to support the finding under review. *Perkin-Elmer*, 732 F.3d at 893.

JMOL should be granted if "a party has been fully heard on an issue and there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a); see *Northview Motors, Inc. v. Chrysler Motors Corp.*, 227 F.3d 78, 88 (3rd Cir. 2000). In a patent infringement action, "JMOL of non-infringement is properly granted if no reasonable jury could have concluded that a limitation recited in the properly construed claims is found in the accused device, either literally or under the doctrine of equivalents." *Medtronic, Inc. v. Advanced Cardiovascular Systems, Inc.*, 248 F.3d 1303, 1309 (Fed. Cir. 2001).

To overcome a motion for JMOL, the non-moving party must point to "substantial evidence" to support a finding in its favor. See *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320, 1329 (Fed. Cir. 1991). Merely "offhand and conclusory statements" are not sufficient to overcome the motion. *Id.* at 1327.

The patent owner bears the burden of proving infringement (by a preponderance of the evidence) that the accused device, or use of that device, has all the limitations of the asserted claims. *Novartis Corp. v. Ben Venue Labs., Inc.* 271 F.3d 1043, 1046 (Fed. Cir. 2001).

B. Smith & Nephew's Accused Probes And The Use Of These Probes Do Not Infringe The Patents In Suit Under The Doctrine Of Equivalents

ArthroCare introduced *no* evidence of infringement under the doctrine of equivalents, and JMOL on this issue should be granted. ArthroCare attempted to introduce evidence regarding equivalent infringement for the first time during redirect examination of its expert Dr. Goldberg. The Court properly excluded this belated "rebuttal" evidence. (D.I. 415 at 1144). In making the ruling, the Court stated that ArthroCare should have brought the matter up during direct examination and that, even if it had, the testimony would not have been permitted because the equivalence analysis in Dr. Goldberg's report was insufficient. (*Id.*). Thus, judgment as a

construction brief (D.I. 246 and 282), to the extent that the Court adopted a different claim construction from that set forth by Smith & Nephew.

matter of law that Smith & Nephew does not infringe any claim of any patent-in-suit under the doctrine of equivalents should be granted.

C. Smith & Nephew Does Not Directly Infringe The Method Claims Of The '592 And '882 Patents

ArthroCare failed to provide *any* evidence that Smith & Nephew itself uses or has used the Saphyre, ElectroBlade, or Control RF probes in surgery as required by the claims of the '592 and '882 method patents. "A method claim is directly infringed *only by one practicing* the patented method." *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) (emphasis added). ArthroCare has offered no evidence from which a reasonable jury could conclude that Smith & Nephew uses its Saphyre, ElectroBlade, or Control RF probes to perform each step of the methods covered by ArthroCare's claims. Indeed, the only evidence at trial was that Smith & Nephew does not use the accused probes. (*See, e.g.*, D.I. 414 at 961). Thus, the Court should enter judgment as a matter of law that Smith & Nephew does not directly infringe any claim of the '882 or '592 patent.

D. The '536 Patent

1. JMOL Of Non-Infringement Of The Claims Of The '536 Patent Is Appropriate Because ArthroCare Failed To Prove That These Probes Are Used As Part Of The "Electrosurgical System"

Claim 45 of the '536 patent, and the claims that depend from it (asserted claims 46, 47, and 56) claim an electrosurgical system, which includes its own fluid supply. Specifically, the '536 patent is directed to an electrosurgical system that can be used in open surgery -- *e.g.*, surgery in a dry environment -- because "[e]lectrically conductive liquid, such as isotonic saline, is directed through a fluid path past a return electrode and to the target site to generate a current flow path." (JTX-1, col. 3, lines 26-30). As described in the Summary of the Invention:²

The above described method is particularly effective in a dry environment (i.e., the tissue is not submerged in fluid), such as open, laparoscopic or oral surgery, because the electrically conducting liquid provides a suitable current flow path from the target site to the return electrode.

² The Summary of the Invention is an optional part of the patent application. "Such summary should, when set forth, be comensurate with the invention as claimed..." 37 C.F.R. §1.73.

(*Id.* at col. 3, lines 37-41). This is distinct from arthroscopic surgery, in which the joint is filled with saline (which is a biocompatible fluid) in order to move the soft tissue out of the way of the surgeon and wash out debris that is produced during the operation. Such a supply of saline in arthroscopic surgery is completely separate from any electrosurgical instrument, and the saline is typically supplied by either an IV bag or a separate system such as the Intellijer.

The Court construed the term "system" in claim 45 of the '536 patent to mean "an assemblage or combination of things or parts forming a unitary whole." (D.I. 354). The claims require that the system include several elements, including "an electrically conducting fluid supply for directing fluid to the target site, "which thus must all be part of the "unitary whole." However, ArthroCare's expert ignored the Court's construction and the requirement that an electrically conducting fluid supply for directing fluid to the target site be part of the claimed system -- *i.e.*, as part of a "unitary whole"—such that the system could be used in open surgery.

Dr. Goldberg testified:

Q. Now, is the Saphyre bipolar ablation probe used as part of an electrosurgical system?

A. Yes, sir, it is.

* * *

Q. Now, is the electrically conductive fluid supply physically connected to this probe that we've been looking at?

A. Not this probe, sir.

Q. So how is it then that this probe is part of a system that includes electrically conductive fluid?

A. Again, *my understanding of a system* is that things don't have to be physically in contact. Another example that just came to mind is when we have a wireless computer system or an audio system, the mouse doesn't have to be connected by a wire to the computer to be part of the same system. They're all functioning to put in the data or to listen to the stereo. *So it doesn't have to be part of, physically connected.* The electrical fluid in the joint will get there. The surgeon has to fill the entire joint to distend it and the fluid will get there. It's all part of the system, sir.

(D.I. 411 at 398-399) (emphasis added).

In his testimony, Dr. Goldberg clearly failed to apply the Court's construction of the term "system." He never described how the Saphyre and a separate fluid supply form an "assemblage or combination of things or parts forming a unitary whole." Instead, he actually disavowed and disagreed with the Court's claim construction, and said that "it doesn't have to be part of, physically connected." (*Id.*). Since he did not agree with the Court's claim construction, he obviously did not provide any evidence that was in accordance with the Court's claim construction. Instead, all he said was that "the fluid will get there." (*Id.*). But he didn't say how.³

These omissions became even more apparent during Dr. Goldberg's testimony regarding the individual claim elements. For each of the accused products, Dr. Goldberg testified that the product comprises the first two elements of the system required by claim 45. However, Dr. Goldberg's analysis ignored the third element of the system, the electrically conducting fluid supply. For the Saphyre, Dr. Goldberg testified:

And there is electrically conducting fluid supplied because this is arthroscopy and there is electrically conductive fluid delivered by the surgeon and the people in the operating room to the joint.

(D.I. 411 at 447). This testimony is very misleading because Dr. Goldberg, and ArthroCare continually focused on arthroscopic surgery. But the claims are not so limited. In fact, if one were to use the Saphyre in, for example, an oral surgery such as described in the Summary of the Invention of the '536 patent⁴ the device would not work because the Saphyre does not have a fluid supply as part of its system. Dr. Goldberg actually recognized this in his experimentation with the Saphyre product (*Id.* at 416):

Q. You mentioned that you also tested the Saphyre when the return electrode was in air and the active electrode was in saline; is that right?

A. Yes, sir.

Q. Can you describe for the jury what happened when you used the Saphyre probe in that mode?

³ Likewise, for the Control RF and ElectroBlade products, Dr. Goldberg failed to provide any evidence that the products are a "system" as required by Claim 45.

A. It didn't work. Thus, any testimony that the Saphyre probe includes the fluid supply simply because it is designed for arthroscopic surgery is misleading and incorrect.

For the Control RF, Dr. Goldberg did not even mention a fluid supply and simply said (*Id.* at 448):

There is electrically conductive fluid, as well as a current flow path when the generator is on.

Similarly, for the ElectroBlade, instead of describing a fluid supply (Tr. at 449):

Up the shaft is a return electrode. It's connected to the generator and it's in electrically conductive fluid and there is a current flow path through the electrically conductive fluid at the time the generator was activated.

While the Smith & Nephew probes are used in the presence of saline or other electrically conducting fluids, that fluid is not supplied to the target site by the probes. (D.I. 415 at 976 and 1013). Fluid, typically from an IV bag, is instead introduced by a separate and distinct piece of medical equipment such as the cannula that is also used for the videoarthroscope. (D.I. 414 at 815-16; D.I. 268, Ex. 43). That separate piece of equipment is not part of the "electrosurgical system." The Smith & Nephew probes and fluid supply are not part of the same assemblage or combination of things or parts forming a "unitary whole."⁵

Moreover, ArthroCare introduced no evidence that the alleged system included a fluid supply "for directing fluid to the target site." Instead, the testimony was uncontroverted that the purpose of the fluid supply used with the Smith & Nephew probes was instead to flood the inside of the joint in order to move soft tissue back and also to wash out debris. (D.I. 414 at 780-81 and 790)

⁵With respect to ArthroCare's attempt to argue that the separate Smith & Nephew Intellijet fluid supply system was part of an "electrosurgical system," that evidence was limited to the "System Configuration" contained in the ElectroBlade IFU. (D.I. 411 at 497; PX 189). However, Karen Drucker testified that this System Configuration is for compliance with European regulations. Thus, to the extent this evidence is taken to support the inference that the ElectroBlade and the Intellijet, used in this configuration, are an "electrosurgical system," it is only evidence for their use in Europe. Moreover, Ms. Drucker explained that IFU showed that the Intellijet system was not completely separate from the ElectroBlade system. (D.I. 415 at 1018).

Since the probes each lack the fluid supply element as part of the electrosurgical system as required by the claims, they cannot directly infringe these claims.⁶ See *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1358-59 (Fed. Cir. 2000); *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991) (“To establish infringement, every limitation set forth in a patent claim must be found in an accused product or process exactly or by substantial equivalent.”). Because ArthroCare failed to present evidence by which a reasonable jury could find that any of the accused products satisfies the “system” requirement of claim 45 that is incorporated into asserted claims 46, 47, and 56, JMOL of non-infringement of these claims is proper.

E. The '592 Patent

1. Smith & Nephew's Accused Probes Do Not Infringe The Claims Of The '592 Patent Because ArthroCare Has Failed To Prove That The Accused Probes Satisfy The Requirement That “The Return Electrode Is Not In Contact With The Body Structure” Or The Requirement Of “Spacing A Return Electrode Away From The Body Structure”

Claim 1 of the '592 patent requires “positioning a return electrode ... such that [it] is not in contact with the body structure” and claim 23 requires “spacing a return electrode away from the body structure.” The Court construed these terms to mean that “the return electrode is not to contact the body structure *at all during the performance of the claimed method.*” (D.I. 353) (emphasis in original).⁷

ArthroCare's expert, Dr. Goldberg, again ignored the Court's claim construction when he rendered his opinion that the Smith & Nephew probes infringe:

Q. Now, does that portion of the claim as construed by the Court require that the Saphyre bipolar ablation probe return electrode never contact the tissue during the course of an entire arthroscopic procedure?

A. No, it doesn't. Mr. Bobrow, you raised a very important --

⁶And, as discussed above, ArthroCare has completely failed to provide any evidence that a separate fluid supply is in any way equivalent to a unitary whole.

⁷Claim 47 of the '536 patent includes a similar limitation which reads “the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue.” Thus, Smith & Nephew submits that ArthroCare failed to prove infringement of that claim for the same reasons.

* * *

A. I was about to try to explain to the members – the ladies and gentlemen of the jury as to why this is a very important point. The claim is talking about a method for applying electrical energy, so the issue is whether or not a device infringes when the electrical energy is not — when it is being applied. There are a lot of parts to a surgery, including putting in the camera, taking out the camera, taking care of the patient that don't involved applying electrical energy. So the key is, is this method being infringed when it's fulfilling the claim which is when the energy is being applied? *So the only way not to infringe this claim with the device is to make sure that the return electrode —*

* * *

is always in contact when the energy is on. And as the videotape and Mr. Marsden suggested, very clearly there is occasional contact frequently, but often there isn't. The probe is designed to enable they're not being contact. If it's not in contact, it's being infringed.

(D.I. 411 at 421-22) (emphasis added).

Dr. Goldberg's testimony that the use of Smith & Nephew's products infringe the claims of the '592 patent is based on ArthroCare's previously-rejected interpretation of the claim term, rather than the Court's construction. Specifically, by stating that the "only way not to infringe this claim with the device is to make sure that the return electrode ... is *always* in contact when the energy is on," Dr. Goldberg is applying ArthroCare's temporal limitation that the Court specifically rejected. (D.I. 352, p. 6) ("Both parties have proposed a claim construction that improperly imports a time limitation into the claim. The claim limitation in dispute has no relation to the time required to perform the method.").

The following chart demonstrates how Dr. Goldberg has ignored the Court's construction and continued to apply ArthroCare's original and now rejected construction:

| ArthroCare's Rejected Argument | Dr. Goldberg's Testimony |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| "Smith & Nephew's proposed experts have not offered any evidence or opinion that the return electrode of the Saphyre is <i>always contacting</i> patient tissue during use." (D.I. 252 at 12) (emphasis added). | "the only way not to infringe this claim with the device is to make sure that the return electrode ... is <i>always in contact</i> when the energy is on." (Tr. at 421-22) (emphasis added). |

Further the Court's claim construction refers to the performance of *all three* steps of the method. Only one of those steps requires the application of RF energy. However, Dr. Goldberg and ArthroCare completely ignored the first step of the method -- "positioning the electrode

terminal into at least close proximity with the target site.” (JTX-3, claims 1 and 23). Both ArthroCare and Dr. Goldberg ignored return electrode contact with the tissue when the probe is being positioned before the RF energy is being applied. This misleading view is evident when Dr. Goldberg states “when we’re talking about *activation of energy, which is what the claims are referring to*, they’re limiting it to *two very small periods of time*.” (D.I. 415 at 1119) (emphasis added). But the Court’s claim construction expressly rejected any time limit, and certainly is not limited to the time period of activation of energy. Thus, Dr. Goldberg’s assertion of “what the claims are referring to” is simply incorrect.

In fact, ArthroCare introduced absolutely no evidence that the method of using the accused products met these limitations of the ’592 patent under the Court’s claim construction. Indeed, even all of its cross-examination of Smith & Nephew’s witnesses was based upon the erroneous claim construction which ArthroCare had proposed, and which the Court had rejected. (See, e.g., D.I. 415 at 983 and 1035-36).

Instead, under the Court’s claim construction, *all* of the evidence at trial showed that the return electrode frequently contacted tissue at various times when one or more of the three steps of the method was being practiced. As can be seen in the various sales-training videos (DTX 315, DTX 316, and DTX 897), the three steps of the method are continually being practiced -- if the power is not being applied, the active electrode is being positioned for the next time that the surgeon applies the power.⁸ Thus, Dr. Goldberg’s and ArthroCare’s evidence was not based on the Court’s claim construction and cannot support a verdict of infringement.

The confusion regarding the time period in which one analyzes the use of the accused devices was further compounded in ArthroCare’s closing argument, in which Mr. Bobrow misleadingly argued:

⁸ ArthroCare attempted to mislead the jury when it twice stopped the Saphyre video at an instant in the middle of the performance of the claimed method when the return was not contacting tissue (D.I. 415 at 985), and suggested this was proof of infringement. The Court’s claim construction was clear: the return electrode is not to contact the body “at all” during performance of the method and the method is not complete until all three steps are performed.

There is no minimum time period. If energy is applied for three seconds and the return electrode is not in contact for those three seconds, and the active electrode is close to the tissue, and RF energy is applied and all the other language is met, this is satisfied. This is satisfied.

Now, *if in the fourth second, it hits the tissue, well, then it's not practicing the method.* But if in the fifth and sixth seconds, it's away from the tissue again, then it is. There is no time limitation.

I can perform this method for two seconds. I could perform it for two minutes. There is no time limitation.

(Tr. at 1580-81) (emphasis added). While this Court indeed held that there were no temporal limitations to the performance of the claimed method, it also held that that "the return electrode is not to contact the body *at all during the performance of the claimed method.*" (4/9/03 Memorandum Order at 2, D.I. 353) (emphasis in original). Thus, if the energy was still on when the return electrode "hits the tissue" in the fourth second of Mr. Bobrow's example, there would be no infringement no matter what happened over the first three seconds.

Finally, ArthroCare presented no direct evidence that doctors do not touch the return electrode to tissue during use of the accused products. In fact, ArthroCare presented no evidence that the doctors who used the devices actually used them to perform the method of the asserted claims. Dr. Goldberg's only opinion, and all that the evidence showed, was that "doctors have used the Saphyre after the [patents' issue] date in the United States." (Tr. at 462; *see also* Tr. 465-66 and 470). There is not one shred of evidence that the uses described by Dr. Goldberg were actually directly infringing the methods of the '592 patent.

Dr. Goldberg ignored the Court's claim construction and presented its infringement case based on ArthroCare's long rejected argument of what the claim means. ArthroCare thus failed to present any relevant evidence by which a reasonable jury could find that the use of any of the three accused products satisfies the return electrode "not in contact" requirement. JMOL of non-infringement is proper.

F. The '882 Patent

1. There Is No Infringement Of The '882 Patent Because The Certificate Of Correction Is Not Valid

The Certificate of Correction broadened the scope of claim 1 of the '882 patent by reducing the number of electrodes required by the claim. Prior to the Certificate of Correction, claim 1 of the '882 patent required four electrodes: an electrode terminal, an active electrode, a return electrode, and an electrically conducting terminal. (JTX-2 at col. 24 lines 8-12). After the Certificate of Correction, the claim required only two electrodes: an electrode terminal and a return electrode. (See Certificate of Correction attached to JTX-2).

It was undisputed at trial that if the Certificate of Correction had not been obtained—or was invalid—Smith & Nephew would not infringe the '882 patent, because the accused Control RF and Saphyre products have only two electrodes. (See testimony of ArthroCare's expert, Dr. Goldberg, (Tr. 1110) (D.I. 415)).⁹

As set forth in Smith & Nephew's brief in support of its motion for a new trial (filed concurrently), Smith & Nephew contends that the issue of validity of the Certificate of Correction should never have been submitted to the jury. However, since it was submitted to the jury, and there was no evidence supporting the jury's finding that the Certificate of Correction was valid, JMOL should be entered for Smith & Nephew on this issue.

The controlling case on the validity of the Certificate of Correction is *Superior Fireplace v. Majestic Products*, 270 F.3d 1358, 1368 (Fed. Cir. 2001). In that case, the Federal Circuit explained that corrections are permitted under 35 U.S.C. § 255 only in order to correct "a mistake of a clerical or typographical nature, or of minor character, which was not the fault" of the PTO. As explained in *Superior Fireplace*, a mistake "of a minor character" may not broaden the claim. 270 F.3d at 1376. Since the Court has already determined here that the Certificate of Correction broadened the claim (D.I. 417 at 1550-51), and ArthroCare's expert Dr. Goldberg admitted as

⁹ ArthroCare tried to create some confusion with the jury by having its expert, Dr. Goldberg, testify that the ElectroBlade product might be viewed as having more than two electrodes. (Tr. at 1111-13). However, this testimony was irrelevant and confusing, since the '882 patent had never

much (D.I. 415 at 1109-11), in order for the Certificate of Correction to be valid, the alleged "mistake" that was "corrected" must therefore qualify as one "of a clerical or typographical nature."

A Certificate of Correction can validly correct a clerical or typographical mistake only if a review of the file history reveals (1) there was indeed a "clerical or typographical mistake" and (2) it is both "manifest" that there is an error to be corrected and it is also "manifest" how to correct the error. 270 F.3d at 1370.

In Smith & Nephew's Opening Brief in Support of its Inequitable Conduct Case, Smith & Nephew showed how the Certificate of Correction at issue was actually obtained by ArthroCare's in-house attorney, John Raffle, in order to broaden the claim so that it could sue Ethicon — in other words, that there was no "mistake" involved at all. (D.I. 442 at 35). However, putting that issue aside, the prosecution history and the testimony from trial shows that no reasonable juror could have found that either the alleged mistake or the solution for correcting the alleged mistake was "manifest," for at least the following four reasons:

a. A Simultaneous Complementary Change to Claim 26 Shows That There Was No Manifest "Error" in Claim 1

Mr. Raffle filed the Request for Certificate of Correction on December 17, 1997. (DTX 306 at 234-35).¹⁰ In the Request for Certificate of Correction, Mr. Raffle represented that the alleged "errors" being corrected arose in connection with an amendment he filed during prosecution of the '882 patent application on March 25, 1997. (DTX 306 at 200-10). One of the alleged errors involved amending application claim 23 (which became patent claim 1) so that the claim required both an "active electrode" and an "electrode terminal." However, in that very same amendment, Mr. Raffle also amended application claim 52 (which became patent claim 26) so that it also required both an "active electrode" and an "electrode terminal." Thus, Mr. Raffle

even been asserted against the ElectroBlade product. (See, e.g., ; Tr. at 1214; see also D.I. 405 at 3).

¹⁰ Although the Request refers to claim "23," it is clear that this was a mistaken reference to the application claim number, and that the request sought to change claim 1. (DTX 306 at 239; D.I. 417 at 1510).

simultaneously amended the claims that would become claims 1 and 26 so that they both included an "active electrode," and an "electrode terminal," (as well as a "return electrode"). (See D.I. 417 at 1511-13):¹¹

Q. So just to review, in Claim 1, in the second — in the third line; you changed active electrode to electrode terminal; right?

A. Yes.

Q. And in the third line of Claim 26, you left active electrode all alone. You didn't change it; right?

A. That's correct.

Q. Okay. And then in the sixth line of Claim 1, you left active electrode again all alone, didn't change it; right?

A. Correct.

Q. And in the corresponding sixth line of Claim 26, you changed active electrode to electrode terminal; right?

A. Correct.

Thus, anyone reviewing the file history of the '882 patent would see that one instance of "active electrode" was changed to "electrode terminal" in both claims 1 and 26, whereas the other instance of "active electrode" in both claims 1 and 26 was left unchanged. Accordingly, no reasonable juror could find that it was "manifest" that the term "active electrode" was in error in claim 1, or that it was "manifest" that "active electrode" should be changed to "electrode terminal" in claim 1.

b. The Amendments To Claims 1 And 26 Created Inconsistent Antecedent Basis Problems — And There Was No Way Of Knowing Which Was Correct

ArthroCare has argued that an error in antecedent basis in claim 1 supports the notion that the so-called "mistake" was "manifest."

Generally, the first time an element is referred to in a claim, an indefinite article ("a" or "an") is used, whereas thereafter, a definite article ("the" or "said") is used to show that the same

¹¹ A side-by-side comparison of Mr. Raffle's amendments to application claims 23 and 52 (which became patent claims 1 and 26 respectively) was used to cross-examine Mr. Raffle at trial. (Exhibit A to accompanying Declaration of William J. Marsden, Jr.)

claim element is being described. To use a definite article for the first mention of a claim term is sometimes referred to as improper "antecedent basis."

In this case, as a result of the amendment Mr. Raffle made to claim 1, the term "active electrode" did not have a proper antecedent basis. (JTX-2, col. 24, lines 5-12). However, anyone reviewing the file history would see that there were other instances in the claims of the '882 patent in which there was an improper antecedent basis. For example, as a result of the amendment Mr. Raffle made to claim 26, at the very same time as his amendment to claim 1, the term "electrode terminal" also did not have a proper antecedent basis. (JTX-2, col. 25, lines 24-30). Thus, anyone reviewing the file history for the '882 patent would see that (a) Mr. Raffle amended claim 1 to include both an "active electrode" and an "electrode terminal," but did not provide proper antecedent basis for the "active electrode," and (b) at the very same time, he amended claim 26 to include both an "active electrode" and an "electrode terminal," but did not provide proper antecedent basis for the "electrode terminal."

Given this, it would not be possible for one reviewing the file history to determine (1) whether any error occurred at all, or if so (2) whether the error was in claim 1 or 26 or both, or (3) whether "electrode terminal" should be "active electrode" or "active electrode" should be "electrode terminal." Certainly, no reasonable juror could possibly find that any of this was "manifest." If anything, to the extent an antecedent basis error would be recognized at all, the most obvious way to correct the error would be to simply change "the" to "an" to correct the antecedent basis.

c. ArthroCare's Failure To Object To The Examiner's Statement Of Reasons For Allowance Shows That There Was No "Manifest Error" In Claim 1

Further, anyone reviewing the file history would see that the Examiner had relied on the alleged "mistake" in claim 1 when deciding to issue the '882 patent, and would thus not think that the alleged error was "manifest."

As is not uncommon, the Examiner provided a statement of his reasons for allowing the '882 patent to issue, which relied on the scope of application claim 23 as of June 22, 1997 — *i.e.*,

before it was broadened by Mr. Raffle's Certificate of Correction (DTX 306 at 222) (emphasis added):

The following is an examiner's statement of reasons for allowance: The prior art of record does not disclose or suggest a method for applying energy to a target site on a patient body structure comprising providing an *electrode terminal* and a *return electrode* electrically coupled to a high frequency voltage source; positioning the *active electrode* in close proximity to the target site in the presence of an *electrically conducting terminal*; and, applying a high frequency voltage between the electrode terminal and the return electrode, the high frequency voltage being sufficient to vaporize the fluid in a thin layer over at least a portion of the electrode terminal and to induce the discharge of energy to the target site in contact with the vapor layer.

As can be seen, the Examiner's Reasons for Allowance was clearly based on the "uncorrected" scope of application claim 23 as it essentially quotes that claim (compare the Reasons for Allowance with application claim 23 as set forth in the Amendment of March 25, 1997, DTX 306 at 201).

Moreover, anyone reviewing the file history would know that such a statement of Reasons for Allowance is binding on the patentee, absent an objection by the patentee. See *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999) (holding that failure to respond to an examiner's reason for allowance functioned as a disavowal of a different interpretation of the claim). Thus, since ArthroCare never objected to the binding statement of Reasons for Allowance, there is simply no way that anyone reviewing the file history would think that it was "manifest" that there was an error in the statement, and thus in claim 1.

d. The Alleged Errors Were Not Even "Manifest" To Mr. Raffle

As shown above, claims 1 and 26 both included an "active electrode" as well as an "electrode terminal," and they both had antecedent basis problems. Mr. Raffle carefully reviewed both claims when the '882 patent issued. (DTX 306 at 235). Yet he only sought a Certificate of Correction with respect to claim 1, and he was perfectly happy to leave claim 26 alone (Tr. 1541) (D.I. 417):

Q. On the certificate of correction, you did not ask to change Claim 26; right?

A. I believe that's correct, yes. Claim 26.

- Q. As issued.
- A. As issued. That's correct.
- Q. You did not ask to correct that?
- A. That's correct.

Thus, to Mr. Raffle himself, the inclusion of both an "active electrode" and an "electrode terminal" in a claim was not a "manifest" error, and an antecedent basis problem with respect to one of those electrodes was also not a "manifest" error. Of course, as shown in Smith & Nephew's Opening Brief in Support of its Inequitable Conduct Case, Mr. Raffle's true motive in seeking the Certificate of Correction was to broaden claim 1 of the '882 patent for ArthroCare's lawsuit against Ethicon, and had nothing at all to do with correcting any actual "errors."

In light of this clear evidence, no reasonable juror could have found either the alleged errors in claim 1 of the '882 patent to be "manifest," or the manner of correcting those alleged errors to be "manifest." Accordingly, JMOL should be entered that the Certificate of Correction is not valid, and therefore that there is no infringement of the '882 patent by the accused Smith & Nephew products.

2. Non-suction Models of Smith & Nephew's Saphyre Products do Not Infringe Claim 54 of the '882 Patent Because ArthroCare Has Failed to Prove that these Products Satisfy the Requirement of "Evacuating Fluid Generated at the Target Site with a Suction Lumen Having a Distal End Adjacent the Electrode Terminal"

Claim 54 of the '882 patent requires evacuating fluid with a suction lumen having a distal end adjacent the electrode terminal. Several of the Saphyre models accused of infringing this claim do not come with suction. Thus, it is impossible for these models to evacuate fluid and infringe claim 54. ArthroCare has admitted that these products do not infringe this claim. D.I. 417 at 1493-94, D.I. 405 at 3. Thus, JMOL of non-infringement of claim 54 is appropriate with respect to these products.

G. **Smith & Nephew Is Not Liable For Contributing To The Infringement Of Any Claim Of The Patents-In-Suit**

Even if ArthroCare had offered evidence of direct infringement by Smith & Nephew customers, ArthroCare has not presented sufficient evidence from which a reasonable jury could find Smith & Nephew liable for contributory infringement under 35 U.S.C. § 271(c). As part of its case-in-chief on contributory infringement, ArthroCare had to prove that Smith & Nephew's probes are not staple articles of commerce suitable for substantial non-infringing uses. See 35 U.S.C. § 271(c). The focus of the analysis of non-infringing uses is the thing actually sold by the accused infringer. *Hodosh v. Block Drug Co.*, 833 F.2d 1575, 1578 (Fed. Cir. 1987). Yet ArthroCare never addressed the non-infringing uses, much less presented evidence that those uses are not substantial.

Indeed, Dr. Goldberg's only testimony on the contributory infringement or the non-infringing uses for Smith & Nephew's probes is:

Q. Now, Dr. Goldberg, the last subject I have for you today has to do with contributory infringement. Have you formed an opinion about whether Smith & Nephew is contributing to the infringement of ArthroCare's asserted claims through its sale of the Saphyre, the Control RF and the ElectroBlade?

A. Yes, I have.

Q. Tell us your opinion, please?

A. Smith & Nephew, by the fact that they are selling this device, teaching folks how to use it in an infringing way, are certainly contributing to the infringement of these patents.

Q. And can you tell us of any documents or other information on which you base your opinion?

A. Well, all the documents we have just gone through, the instructions for use and the sales guides, are clearly pointing, they are teaching to, and providing product to infringe these patents. *And an important point to add, in terms of the contributing to infringement, is that, as I have shown, the documents themselves say that they are selling these devices to be used for arthroscopic surgery, not for other things.*

(Tr. at 499-500) (emphasis added). Not only is this testimony not supported, but it is also facially misleading and prejudicial. As discussed above, the patents-in-suit are not limited to arthroscopic

devices and methods, and in fact are directed to open surgeries. ArthroCare's continual emphasis on arthroscopic products wrongly suggested to the jury that, since ArthroCare's *commercial* products are arthroscopic devices, Smith & Nephew's arthroscopic devices must infringe. This was unfair and misleading.

As described above, Dr. Goldberg's opinions that the use of Smith & Nephew's probes infringe the patents-in-suit lack sufficient factual support, ignore the Court's claim construction, and was not disclosed in Dr. Goldberg's expert report. Even if one accepts Dr. Goldberg's findings of infringement, it is readily apparent and uncontested that there are substantial non-infringing uses for the accused products that do not infringe the asserted claims of the patents-in-suit. In fact, there are numerous non-infringing uses for each of the accused products.

Examples of uses of the accused products that do not infringe the '592, '882, and '536 patent claims are using the probes to apply energy while the return electrode is in contact with tissue, using the probes to apply energy without creating a vapor layer, and using the probes as part of an electrosurgical system that does not have a fluid supply as part of a "unitary whole" electrosurgical system.

Dr. Goldberg has testified that the accused products infringe the claims of the '592 patent because in use they are *not always* in contact with tissue while energy is being applied. (Tr. at 421-22). In reaching this conclusion, Dr. Goldberg recognized that the return electrode of the accused devices does frequently touch tissue while power is being applied. (Tr. at 421-22) ("as the videotape and Mr. Marsden suggested, very clearly there is occasional contact frequently ..."). It is thus uncontested that using Smith & Nephew's probes to apply energy while the return electrode is in contact with tissue is a non-infringing use of these probes even under Dr. Goldberg's description of what constitutes infringement.

Absent some evidence that these the non-infringing uses of Smith & Nephew's probes (*i.e.*, use with the return electrode in contact with tissue) are not substantial non-infringing uses, no reasonable jury could conclude that Smith & Nephew is liable for contributory infringement.

H. Smith & Nephew is Not Liable for Inducement of Infringement of Any Claim of the Patents-in-Suit.

Nor has ArthroCare offered evidence sufficient to support a finding that Smith & Nephew has actively induced others to infringe any of the claims under 35 U.S.C. §271(b). To be liable for active inducement, the inducer must have "possessed the specific intent to encourage another's infringement and not merely that the defendant had knowledge of the acts alleged to constitute infringement." *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 553 (Fed. Cir. 1990). To prove inducement, ArthroCare bears the burden of proving first that Smith & Nephew's customers directly infringe, for there is no liability for inducement without a corresponding act of direct infringement. *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 774 (Fed. Cir. 1993); *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 604 F. Supp. 1485, 1487 (D. Del. 1985), *overruled on other grounds*, *National Presto Industries, Inc. v. West Bend Co.*, 76 F.3d 1185 (Fed. Cir. 1996) ("There can be no liability for inducement of infringement under section 271(b) unless an actual infringement in violation of section 271(a) is induced."). ArthroCare must also prove that Smith & Nephew induced that direct infringement. *Manville Sales*, 917 F.2d at 553. Additionally, ArthroCare must show that Smith & Nephew had actual intent to cause the acts which constitute the infringement *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1468-69 (Fed. Cir. 1990).

ArthroCare offered no evidence that any customer of Smith & Nephew has *ever* used any one of the accused probes in a way that meets all of the limitations of any of the claims in suit. Indeed, the only evidence ArthroCare introduced about how Smith & Nephew customers use the products came from Smith & Nephew clinical evaluation surveys, which do not address most, much less all of the elements required by the claims. (D.I. 410 at 466, 471, and 484).

In addition, ArthroCare did not prove that Smith & Nephew *intends* to cause others to infringe any of the claims of the patents in suit. ArthroCare argued for the admissibility of otherwise inadmissible and highly prejudicial copying evidence, claiming that such evidence was relevant to show the intent to cause infringement element of its inducement charge. (Tr. at 24-

25). ArthroCare's "copying" story, which consisted only of an *ad hominem* attack and evidence that Smith & Nephew looked at certain ArthroCare products (with no evidence of actual copying), was wholly insufficient to show that Smith & Nephew actively induces any such infringement. Moreover, ArthroCare introduced no "evidence" of "copying" related to the Saphyre product.

ArthroCare also attempted to rely on evidence that Smith & Nephew instructs users to avoid contacting *non-target* tissue with the return electrode of the Saphyre product. (Tr. at 486). In arthroscopy, there is a well-recognized distinction between target and non-target tissue. Philip Eggers, one of the co-inventors of all three patents in suit, testified that tissue such as the meniscus is an example of target tissue and tissue such as cartilage is an example of non-target tissue. (Tr. at 351-352). Smith & Nephew does not instruct users to avoid contact with *any* tissue, it only instructs users to avoid contact with *non-targeted* tissue. Thus, ArthroCare's supposed evidence that Smith & Nephew is inducing infringement of the '592 patent claims by instructing surgeons not to contact non-targeted tissue with the Saphyre probe does not support Dr. Goldberg's conclusion, and, in fact, contradicts it.

ArthroCare's evidence is insufficient to support a finding that Smith & Nephew's customers or users actually use the accused probes in a way that directly infringes any of the claims, much less that Smith & Nephew actively induces them to do so.

I. Because The Relevant Factual Evidence Is Undisputed, This Court Should Find The Asserted Claims Of The Patents-In-Suit Invalid As A Matter Of Law

It is well recognized that a finding of invalidity requires proof by clear and convincing evidence. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996). Nonetheless, where the relevant facts are undisputed—whether the references are prior art and what those references disclose—a jury may not simply ignore those facts to find the patent valid. *See Verdegall Brothers, Inc. v. Union Oil Company Of California*, 814 F.2d 628, 632 (Fed. Cir. 1987) (granting JNOV based on the "uncontradicted disclosure" of a prior art reference); *see also IPPV Enterprises, LLC v. Echostar Communs. Corp.*, 191 F. Supp. 2d 530, 561-62 (D. Del. 2002)

(granting JMOL based on "undisputed evidence" that the patent was invalid as anticipated and finding that no reasonable jury viewing the documentary evidence . . . could fairly conclude otherwise"). If the prior art references show that all of the limitations of a patent claim are present, the trial court is *required* to enter JMOL of anticipation. *See id.*; *Anderson v. Liberty Lobby*, 477 U.S. 242, 250-51 (1986) ("The trial judge must direct a verdict if, under the governing law, there can be but one reasonable conclusion as to the verdict."); *Richardson-Vicks, Inc. v. Upjohn Co.*, Civ. Action No. 93-556-SLR, 1996 WL 31209 (D. Del.), *aff'd* 122 F.3d 1476 (Fed. Cir. 1997). (entering JMOL of invalidity where "the evidence, viewed in a light most favorable to plaintiff, nevertheless compels a verdict contrary to that of the jury").

1. There Are No Factual Disputes Relating To Validity

In the present case, there are *no* factual disputes relating to validity. First, there is no dispute that the six references relied on by Smith & Nephew are prior art. Moreover, there is no real dispute about the relevant disclosures of these references, or of the patents-in-suit.

Smith & Nephew proved by clear and convincing evidence that each of the asserted claims of the patents-in-suit is invalid. Its expert, Dr. Taylor, showed how—on a limitation-by-limitation basis—various prior art patents and articles anticipate the asserted claims of the '536 (D.I. 416 at 1294-1313), '882 (D.I. 416 at 1313-25) and '592 (D.I. 416 at 1325-34) patents. Similarly, Dr. Manwaring, one of Smith & Nephew's other experts, also showed that the '882 patent is invalid. (D.I. 414 at 883-96). ArthroCare, on the other hand, failed to put forth *any* evidence to rebut Smith & Nephew's *prima facie* showing of invalidity, and called no witnesses to testify on validity. Thus, ArthroCare failed to meet its burden to introduce rebuttal evidence showing that the claims are valid. *U.S. Environmental Prods. Inc. v. Westall*, 911 F.2d 713, 716 (Fed. Cir. 1990) (holding that once a defendant demonstrates a *prima facie* case of invalidity, the patent holder must come forward with convincing evidence to rebut the showing); *see also Hycor Corp. v. Schlueter Co.*, 740 F.2d 1529, 1537 (Fed. Cir. 1984).

Instead, all ArthroCare did was cross-examine Smith & Nephew's experts. But ArthroCare's cross-examination fell far short of creating a record that can support the jury's

verdict that the asserted claims are valid. Nothing brought out in the cross-examinations of Drs. Taylor and Manwaring undermined the limitation-by-limitation analysis presented by these experts. ArthroCare's counsel merely cited irrelevant concessions related to claim construction arguments that ArthroCare had proposed, and that this Court had already rejected. In light of the verdict of validity, ArthroCare's focus on irrelevant cross-examination topics clearly confused the jury, since none of these "concessions" rebutted Smith & Nephew's clear and convincing evidence of invalidity. Thus, no reasonable jury could have failed to have found the patents invalid, and the jury's verdict cannot stand. *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998).

2. The '536 Patent

Smith & Nephew proved by clear and convincing evidence that the asserted claims of the '536 patent are invalid. Specifically, Dr. Taylor provided a limitation-by-limitation analysis of how the Elsässer and Roos Article (DTX 59A and 59B; D.I. 416 at 1294-1300), the Roos '198 patent (DTX 11; D.I. 416 at 1300-05), the Doss '007 patent (DTX 17; D.I. 416 at 1305-09), and the Pao '499 patent (DTX 21; D.I. 416 at 1309-13) each anticipate the asserted claims of the '536 patent. ArthroCare provided *no* rebuttal evidence to contradict Dr. Taylor's testimony, and instead relied on its cross-examination of Dr. Taylor to do nothing more than confuse the jury. However, Dr. Taylor did not waver or contradict his testimony during cross-examination, and his testimony did not provide ArthroCare with the rebuttal evidence it needed to overcome Smith & Nephew's *prima facie* case of invalidity.

a. The Pao '499 Patent

Perhaps the most obvious example of how ArthroCare confused and misled the jury, and of the jury ignoring the evidence with respect to the issue of invalidity involves the Pao '499 patent (DTX 21, Exhibit hereto). In his direct testimony, Dr. Taylor showed how the Pao '499 patent disclosed every limitation—on a limitation-by-limitation basis—in claims 46 and 56 of the '536 patent, as well as the unasserted independent claim 45 (D.I. 416 at 1309-13; Exhibit B).

In its cross-examination of Dr. Taylor relating to the Pao '499 patent (D.I. 416 at 1405-12), ArthroCare only asked him about one claim limitation—"the return electrode being sufficiently spaced from the electrode terminal to minimize direct contact between the return electrode and the patient's tissue." But this is a limitation that is found *only* in claim 47 of the '536 patent (see JTX-1, claim 47 at col. 18, lines 32-36), which is the one claim against which Smith & Nephew did *not* assert the Pao '499 patent. (D.I. 416 at 1728). Thus, ArthroCare's cross-examination of Dr. Taylor on this issue was completely irrelevant and misleading.

Since ArthroCare did not offer any rebuttal evidence and did not even cross-examine Dr. Taylor with respect to any other claim term, it was *undisputed* at trial that the Pao '499 patent anticipates claims 45, 46, and 56 of the '536 patent. Yet the jury found otherwise. Thus, JMOL of invalidity of these claims *must* be entered. *Verdegaal Bros.*, 814 F.2d at 632; *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

b. The Doss '007 Patent

In his direct testimony, Dr. Taylor also showed how the Doss '007 patent (DTX 17, Exhibit 3) disclosed every limitation—on a limitation-by-limitation basis—of claims 45, 46, and 47 of the '536 patent. (D.I. 416 at 1305-09; Exhibit C). In its cross-examination of Dr. Taylor, ArthroCare asked him about only two claim limitations: "return electrode" and "connector located at the proximal end of the shaft." See JTX-1, claim 45 at col. 18, lines 18-22.¹² But once again ArthroCare failed to elicit any testimony that Smith & Nephew's invalidity case.

i. Return Electrode

Dr. Taylor explained that the Doss '007 patent discloses a return electrode under the Court's claim construction. (D.I. 416 1306-07, 1455-57). ArthroCare did not introduce any contrary testimony, and Dr. Taylor did not waver in his opinion on cross-examination. Instead of seeking any relevant testimony, ArthroCare asked a series of irrelevant and misleading questions regarding possible tissue effects by the return electrode. (D.I. 416 at 1380-99).

¹² These limitations are found in independent claim 45. "Since the patentee [] does not argue the validity of the dependent claims separately, their validity will stand or fall with the independent claim [45]." *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1480 (Fed. Cir. 1997).

First, ArthroCare asked Dr. Taylor whether the term "return electrode" was explicitly used in the Doss '007 patent. (D.I. 416 at 1380). ArthroCare was apparently trying to mislead the jury by suggesting that the words "return electrode" must be explicitly disclosed or the reference does not anticipate. This is clearly wrong, as claim limitations can be inherently found in a reference. See *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999); see also *Tyler Refrigeration v. Kysa Ind. Corp.*, 777 F.2d 687, 689 (Fed. Cir. 1985). Thus, ArthroCare's attempt to show that an inherent limitation is not explicitly disclosed does not rebut Smith & Nephew's anticipation case. *MEHL/Biophile Int'l Corp.*, 192 F.3d at 1366; *Verdegaal Bros., Inc. v. Union Oil Co. of Cal.*, 814 F.2d 628, 630 (Fed. Cir. 1987).

ArthroCare then set out on a path of questioning that not only ignored the Court's construction of the claim term "return electrode," but also reargued the claim construction that it had originally proposed and that the Court had rejected. ArthroCare had sought a claim construction that the return electrode would have minimal tissue effect. (Joint Claim Construction Statement) (D.I. 270 at 9). The Court squarely rejected ArthroCare's proposed claim construction, and instead held that "[a]s contrasted with an active electrode, the term 'return electrode' means 'an electrode having a larger area of contact than an active electrode, thus affording a lower current density.'" (4/19/03 Memorandum Order at 4) (D.I. 353). Yet ArthroCare ignored the Court's claim construction, and attempted to mislead the jury by asking questions related to tissue effect by the return electrode. At this point in the trial, the Court expressed some concern that the question may be misleading "because it is maybe inconsistent with what I've said." (D.I. 416 at 1389). The Court went on:

THE COURT: Well, if you are saying there is no difference between the two, I mean I do believe that under this definition there has to be a difference between the active and the return. If you are saying and your point is that in the [Doss] prior-art reference there is no difference between the two, then that is an appropriate line of cross.

ArthroCare's counsel then assured the Court that that was his intention to show specifically that there was no difference between the two electrodes. (D.I. 416 at 1389-90). However, following this interchange, ArthroCare did not attempt to show that there is no

difference between the two, but instead went right back to asking about tissue effects (D.I. 416 at 1396):

Q. So again, my question, sir, simply is, is each electrode designed to cause a tissue effect?

A. Yes.

This line of questioning is clearly misleading as it fails to take into account the Court's claim construction, which permits the return electrode to have a tissue effect. Moreover, Dr. Taylor's answer in no way contradicts his prior testimony, nor his testimony on redirect (D.I. 416 at 1455-57) (emphasis added):

Q. Did you use the Court's definition of return electrode in determining whether or not the Doss reference had a return electrode?

A. Yes.

Q. And what is the critical element of the Court's definition of whether or not something constitutes a return electrode?

A. *The critical element is an electrode having a larger area of contact than an active electrode, thus affording a lower current density.*

Q. And when you reviewed the Doss patent, did you find such an electrode?

A. Yes. The outer electrode is -- just look at the geometry --

* * *

And just on the basis of plane geometry if you assume both electrodes have the same thickness, the outer electrode will have more surface area.

Q. And does that outer electrode meet the Court's definition of a return electrode?

A. I believe it does.

Thus, ArthroCare failed to rebut Dr. Taylor's clear and convincing testimony that the Doss '007 patent discloses a return electrode.

ii. Connector Near the Proximal End of the Shaft

Dr. Taylor testified that the Doss '007 patent discloses a connector near the proximal end of the shaft (D.I. 416 at 1307), pointing specifically to col. 3, lines 30-34, which provides as follows:

Reference is made to Fig. 9 which schematically shows a two-electrode embodiment of the invention. A source of alternating voltage 12 such as a radio-frequency generator producing a 0.1 to 20 megahertz electric current is operably connected to electrodes 14 and 16.

This disclosure clearly meets this Court's interpretation of "connector" (4/9/03 Memorandum Order at 2) (D.I. 353):

The word connect means "to bind or fasten together; join or unite; link[.]" The word "connector," in terms of the '536 patent, shall be construed to mean a "structure that electrically links the electrode terminal to the high frequency power supply."

In its definition, the Court did not require that the connector be removable. Thus, a wire that passes through the proximal end of the device as shown in Figs. 7 and 9 of the Doss '007 patent would be a "connector" under the Court's construction.

However, in its cross-examination, ArthroCare once again ignored the Court's claim construction, and asked only whether the location of the connector was explicitly disclosed (D.I. 416 at 1400):

Q. And here in the Doss '007 patent, would you agree with me that there is no disclosure of where the connector is located, in other words, there is nothing that tells you where the connector is located with respect to the shaft?

A. Hold on a second. I believe that's correct. There is no specific mention of the location of that.

As discussed above, this is both misleading and legally incorrect because elements that are inherently disclosed still anticipate. Therefore, ArthroCare did not rebut Dr. Taylor's testimony that the Doss '007 patent discloses a connector near the proximal end of the shaft. *Verdegaal Bros.*, 818 F.2d at 631; *IPPV Enterprises, LLC*, 191 F. Supp. 2d at 561-62.

Because the return electrode and connector elements were the only ones that ArthroCare even attempted to demonstrate were not in the Doss '007 patent, and because ArthroCare patently

failed in that attempt, ArthroCare did not rebut Smith & Nephew's *prima facie* case that the claims 45, 46, and 47 of the '536 patent are invalid as anticipated by the Doss '007 patent and JMOL of invalidity should be entered based on this reference. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

c. The Elsässer and Roos Article and the Roos '198 Patent

In his direct testimony, Dr. Taylor showed how both the Elsässer and Roos Article (DTX 59A and 59B) and the Roos '198 patent (DTX 11, Exhibit 5) disclosed every limitation—on a limitation-by-limitation basis—of claims 45, 46, 47, and 56 (Ross '198) and 45, 46, and 56 (Elsässer and Roos Article) of the '536 patent (D.I. 416 at 1294-1305; Exhibits D and E). In its cross-examination of Dr. Taylor relating to these references, ArthroCare asked him only about two claim limitations—"electrically conducting fluid" and "connector near the proximal end of the shaft." See JTX-1, claim 45 at col. 18, lines 18-25. Again, the validity of the dependent claims, which ArthroCare did not separately challenge, stands or falls with the independent claim. *Richardson-Vicks*, 122 F.3d at 1480. And again, ArthroCare failed to rebut Smith & Nephew's clear and convincing invalidity proof.

i. Connector Near the Proximal End of the Shaft

ArthroCare cross-examined Dr. Taylor with respect to the "connector" limitation in the Roos '198 patent, but not with respect to the Elsässer and Roos Article. In any event, it was undisputed at trial that the Roos '198 patent and the Elsässer and Roos Article both disclose a connector at the proximal end of the shaft (DTX 11 at col. 7, lines 1-7) (emphasis added):

In the present embodiment, two leads 16 pass outwards from the cylindrical neutral electrode 11, which at 20 are combined to form a single cable, *leading to the rear end of the endoscope* 13. The neutral electrode 11 is connected via a further insulated cable 14 to the high frequency generator...

Figure 7 and claim 1 further disclose a connector (DTX 11 at col. 7, lines 51):

Insulated cable means for connecting said treatment electrode to one pole of a high-frequency generator...

Similarly, Figure 9 of the Elsässer and Roos Article clearly shows a removable connector near the proximal end of the endoscope. (DTX 59A at 133, Fig. 9) (Marsden Dec. Ex. 6)

It is clear that these disclosures in the Roos '198 patent and the Elsässer and Roos Article satisfy the limitation "connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply," as construed by the Court. First the Court held that the term "connector" simply means "a structure that electrically links the electrode terminal to the high frequency power supply." (4/9/03 Memorandum Order at 2) (D.I. 353). In its definition, the Court did not require that the connector be removable. Thus, a wire that passes through the proximal end of the device would be a connector under the Court's construction. The Roos '198 patent at Figure 7 and col. 7, lines 1-7 and the Elsässer and Roos Article at Figure 8 both show that all the wires lead to the rear (proximal end) of the endoscope. Thus, both references disclose a connector that is located at the proximal end of the shaft.

Second, Dr. Taylor testified that the Roos '198 patent and the Elsässer and Roos Article each disclose a connector near the proximal end of the shaft. (D.I. 416 at 1298 and 1302-03, respectively; *see also* Exhibits D and E). For example, Dr. Taylor explained how the Roos '198 patent discloses a connector at the proximal end of the shaft (D.I. 416 1301-03) (emphasis added):

Q. Have you done an element-by-element comparison of the teachings of the Roos '198 with the claims of the '536 patent?

A. Yes, I have.

* * *

A. ... A connector, requires a connector, coupling the shaft to the electrosurgical power supply. And that element is satisfied by Figure 7 and the text in Column 7, Lines 1 through 5. And also in Claim 1, as described here in this text. So that element is satisfied.

Dr. Taylor also explained that the disclosure of the connector in the Roos '198 patent was inherent (D.I. 416 at 1371-72):

A. You do realize that all resectoscopes have connectors at the back end of the resectoscope.

* * *

A. There is nothing in the '198 patent that says it explicitly. But there are no resectoscopes on the market that don't have a connector at the end, on the back of the resectoscope.

ArthroCare again did not introduce any contrary testimony and Dr. Taylor never wavered in his opinion. Instead, ArthroCare only asked whether the location of the connector was *explicitly* described in the Roos '198 patent (D.I. 416 1371). These questions were irrelevant since elements do not have to be explicitly recited to be found in a prior art reference. See *MEHL/Biophile*, 192 F.3d at 1365; *Tyler Refrigeration*, 777 F.2d at 687.

Further, ArthroCare did not present *any* evidence, not even through cross-examination, to contradict Dr. Taylor's testimony that the Elsässer and Roos Article discloses a connector at the proximal end of the shaft. And ArthroCare did not ask a single question about the connector's location in the Elsässer and Roos Article.

ii. Electrically Conducting Fluid

The other issue on which ArthroCare cross-examined Dr. Taylor related to the "electrically conducting fluid" limitation. Despite ArthroCare's lengthy cross-examination of Dr. Taylor, it was *undisputed* at trial that claim 1 of the Roos '198 patent and the Elsässer and Roos Article both explicitly disclose electrically conducting fluid. Claim 1 of the Roos '198 patent reads:

[A] space being formed between said treatment electrode and said neutral electrode which is adapted to be filled with *liquid to provide electrical conductance* between said electrodes.

(DTX 11 at col. 7, lines 59-62) (emphasis added). Similarly, the Elsässer and Roos Article also explicitly discloses electrically conducting fluid:

[The device] offer[s] the high-frequency current a path to balance the potential difference that would be so short and *offer such a low resistance* that aberrant currents or leakage currents do not even occur... The *current flows directly from the cutting loop to the neutral electrode through* the adjacent tissue to be cut *and the irrigation liquid*.

(DTX 59B at 4) (emphasis added).

It is clear that the "liquid to provide electrical conductance" in claim 1 of the Roos '198 patent and the "irrigation liquid" which "offer[s] such a low resistance" in the Elsässer and Roos Article are both the same as "electrically conductive fluid" as used in the '536 patent, for at least two reasons.

First, the words used in claim 1 of the Roos '198 patent and in the Elsässer and Roos Article both clearly meet this Court's interpretation of "electrically conductive fluid" (4/9/03 Memorandum Order at 3) (D.I. 353):

"[E]lectrically conducting fluid" and "electrically conductive fluid" shall be construed to mean "any fluid that facilitates the passage of electrical current."

In its definition, all the Court required was that the fluid "facilitate[]" the passage of electrical current." Of course, a "liquid" is a type of "fluid," and since "facilitate" means simply "to make easier," a "liquid to provide electrical conductance" in claim 1 of the Roos '198 patent squarely meets this Court's definition of "any fluid that facilitates the passage of electrical current." Similarly, the "irrigation liquid" that "offer[s] such a low resistance" would clearly "facilitate the passage of electrical current."

Second, the testimony at trial was *undisputed* that the Roos '198 patent and the Elsässer and Roos Article both disclose the use of electrically conducting fluid. Dr. Taylor testified that the Roos '198 patent and the Elsässer and Roos Article each disclose electrically conducting fluid. (D.I. 416 at 1299 and 1303, respectively). For example, Dr. Taylor explained that claim 1 of the Roos '198 patent explicitly discloses electrically conducting fluid (D.I. 416 at 1301-03) (emphasis added):

A. ... The Roos '198 patent basically follows up on the work that Doctors Elsässer and Roos did in their article and it's a bipolar electrosurgical device for the treatment of prostate and bladder tissue, commonly known as TURP.

* * *

It also requires an electrically conducting fluid supply, directed to the target site and generating current, flow path between the active and return electrode. That is diagrammatically shown here in Figures 7 and 8 and also specifically called out in Claim 1, basically the last line in Claim 1. So that element is satisfied.

Q. Just to pause on this one for a moment, that language that is quoted below the [demonstrative exhibit] drawing comes from Claim 1 of the Roos '198 patent?

A. That's correct.

Q. That is where you found support for the electrically conduct[ing] fluid limitation?

A. Yes.

ArthroCare did not introduce any contrary testimony, and did not call its own expert Dr. Goldberg to testify in rebuttal to Smith & Nephew's invalidity case. Dr. Taylor never changed his opinion. Instead, ArthroCare's strategy was to once again mislead the jury by having Dr. Taylor "admit" irrelevant facts that in no way contradicted or overcame the fact that these references disclose electrically conducting fluid.

For example, Dr. Taylor testified under cross-examination that the Roos '198 patent and the Elsässer and Roos Article do not use the words "saline" or "ringer's lactate." (D.I. 416 at 1375). However, this line of questioning was misleading since the asserted claims of the '536 patent do not require that the electrically conducting fluid be saline or ringer's lactate.¹³ Thus, ArthroCare failed to rebut Dr. Taylor's clear and convincing testimony that these references disclose an electrically conducting fluid under the Court's claim construction.

ArthroCare also questioned Dr. Taylor about how some other prior art monopolar TURP devices used glycine or other non-conductive fluids (D.I. 416 at 1339), apparently trying to suggest some connection between TURP procedures and non-conductive fluids.¹⁴ However, such a suggestion does not change the unchallenged fact that claim 1 of the Roos '198 patent explicitly discloses using electrically conducting fluid as Dr. Taylor testified.

ArthroCare also attempted to confuse the jury by pointing to embodiments in the Roos '198 patent that used contact between the return electrode and the tissue to provide some of the electrical connection. (D.I. 416 at 1345). However, Dr. Taylor pointed out that "this is not the embodiment that I talked about and it's not an embodiment that I described." (*Id.*). ArthroCare's focus on other embodiments is misleading. It is well-settled that all that is needed to anticipate is one anticipating embodiment or disclosure, even if other embodiments might not anticipate. See

¹³ The saline limitation is found only in asserted claims 11 and 32 of the '592 patent. The references Smith & Nephew relied upon for anticipation of the '592 patent, the Doss '007 patent and the Slager article, explicitly disclose saline.

¹⁴ The Roos '198 patent and Elsässer and Roos Article both describe devices that can be used in procedures other than TURP (DTX-11 at Col. 1, lines 18-22; DTX-59B at 5).

Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc., 127 F.3d 1065, 1068 (Fed. Cir. 1997) (holding that the district court erred in limiting the disclosure to the non-anticipating preferred embodiment when the other embodiments may anticipate). Therefore, this line of questions also did not rebut Dr. Taylor's direct testimony.

Finally, ArthroCare pointed to a later-issued patent, the Roos '667 patent. (PX-605) (Tr. at 1359-70). However, Dr. Taylor testified that the Roos '667 patent was irrelevant to his opinion that electrically conductive fluid was used in the Roos '198 patent (D.I. 416 at 1365-66) and ArthroCare adduced no evidence to the contrary.

None of Dr. Taylor's cross-examination testimony in any way contradicted his direct testimony, or the explicit disclosures of the references, that both the Roos '198 patent and the Elsässer and Roos Article clearly disclose an electrically conducting fluid. Thus, because ArthroCare put on no other evidence on this point, ArthroCare has not rebutted Smith & Nephew's *prima facie* case that the asserted claims of the '536 patent are invalid as anticipated by the Elsässer and Roos Article and the Roos '198 patent, and JMOL of invalidity of claims 46, 47, and 56 based on these references is clearly warranted. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

3. The '882 Patent

Smith & Nephew also proved by clear and convincing evidence that the asserted claims of the '882 patent are invalid. Specifically, Dr. Taylor provided a limitation-by-limitation analysis of how the Manwaring '138 patent (DTX 46; D.I. 416 at 1313-17) anticipates claims 1, 13, and 54 and the Slager Article (DTX 65; D.I. 416 at 1317-20) anticipates claims 1, 13, 17, and 54 of the '882 patent. Dr. Manwaring, one of Smith & Nephew's other experts, also testified that the Manwaring '138 patent anticipated claims 1, 13, and 54 of the '882 patent. (D.I. 416 at 886-96). Dr. Taylor further testified that the asserted claims are invalid as not enabled under 35 U.S.C. § 112, because the supposed new process of "coblation" is not adequately described to differentiate it from the prior art. (D.I. 416 at 1320-25).

ArthroCare once again provided no rebuttal evidence to contradict Dr. Taylor's and Dr. Manwaring's testimony, and instead relied on its cross-examination of these experts to confuse and mislead the jury. However, neither Dr. Taylor nor Dr. Manwaring wavered or contradicted their testimony during cross-examination, and their testimony went un rebutted.

a. The Slager Article

In its cross-examination of Dr. Taylor relating to the Slager Article (DTX 65), ArthroCare asked about two claim limitations—"at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum" and "evacuating fluid generated at the target site"; as well as a portion of the preamble to claim 1 of the '882 patent—"applying energy to a target site on a patient body structure." However, ArthroCare failed to rebut Smith & Nephew's *prima facie* case of invalidity of the '882 patent.

i. UV Photons

Dr. Taylor testified that the Slager Article discloses energy in the form of photons having a wavelength in the ultraviolet spectrum (UV photons), which is a limitation in claim 13. (D.I. 416 at 1319; Exhibit F). ArthroCare did not introduce any contrary testimony. Instead, ArthroCare attempted to mislead the jury by suggesting that, because UV photons were not explicitly disclosed, UV photons were not present at all. (D.I. 416 at 1419-21).

However, Dr. Taylor explained, in detail, why the production of UV photons is inherently disclosed in the Slager Article based on principles of elementary chemistry:

Q. So just from seeing a spark, just from seeing that flash of light with the naked eye, you can't tell whether or not there is ultraviolet light in there or whether there isn't. True?

A. *That's true, except you can't have a spark in aqueous solution without the UV light.*

* * *

Q. So you didn't do any tests and you didn't look at the literature; correct?

A. *Right. One has to realize, though, that if you have a spark in an aqueous solution, especially a sodium chloride aqueous solution, that you will generate UV photons because of the transition of the hydroxyl ion. You will*

also generate what we would consider to be orange, yellowish-orange light, 580 nanometers, because of the sodium ion transition. That is college chemistry.

(D.I. 416 at 1419-20) (emphasis added).

Dr. Taylor's testimony that the Slager Article inherently discloses the production of UV photons was not rebutted by ArthroCare, and therefore, for purposes of anticipation analysis, it does contain that limitation. *See generally Verdegaaal Brothers*, 814 F.2d at 631 (holding that a patent claim is anticipated by a reference that either explicitly or inherently discloses all of the claim limitations).

ii. Evacuating Fluid Generated at the Target Site

Dr. Taylor also testified that the Slager Article discloses evacuating fluid (bubbles) generated at the target site, which is a limitation in claim 54. (D.I. 416 at 1320; Exhibit F). ArthroCare did not introduce any contrary testimony and Dr. Taylor never wavered on cross-examination. Instead, ArthroCare again attempted to mislead the jury by suggesting that, because the exact suction technique was not explicitly disclosed, that a suction lumen adjacent the electrode terminal is not disclosed. (D.I. 416 at 1425-26).

iii. Applying Energy to a Patient Body Structure

Dr. Taylor testified that the Slager Article anticipates claim 1 of the '882 patent. (Tr. at 1319; Exhibit F). Again, ArthroCare did not introduce any contrary testimony and instead attempted to mislead the jury by suggesting that, because the tissue used by Slager was a piece of aorta in a lab dish, the Slager Article did not disclose a "method for applying energy to a target site on a patient body structure" as set forth in the preamble of the '882 patent. (Tr. at 1426-28).

The reference to "patient body structure" merely sets forth the intended environment of use in the preamble of the claim, and does not constitute a claim limitation. *See Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1346-47 (Fed. Cir. 2002); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1373-75 (Fed. Cir. 2001).

Moreover, ArthroCare's suggestion is completely undercut by the position it took with respect to conception and reduction to practice of claim 1 of the '882 patent. In particular, in

order to avoid some of Smith & Nephew's prior art, ArthroCare asserted that claim 1 of the '882 patent was reduced to practice by June 18, 1993. (DTX 406). However, Philip Eggers, one of the inventors of the patents-in-suit, testified that as of 1993 his experiments had not progressed to being used in live patients, but only involved chicken parts in bowls of saline (D.I. 410 at 295):

Q. My question to you, Mr. Eggers, is: As of January 25, 1993, or February 8, 1993, the development of your invention had not progressed to the point that it was being used on actual patients; right?

A. That's correct.

Q. It was only being used in experiments in bowls of saline on various chicken parts; right?

A. Correct.

Thus, the inventor himself believed that experiments in bowls of saline were covered by methods of applying energy to a target site on a body structure.¹⁵ ArthroCare cannot have it both ways. If experiments on chicken parts in bowls of saline were sufficient to constitute reduction to practice of a "method for applying energy to a target site on a patient body structure," then a prior art method involving human aorta tissue in a lab dish certainly must also qualify as such a method. Accordingly, ArthroCare did not rebut Dr. Taylor's testimony, nor did it contradict his conclusion that the Slager Article anticipates the asserted claims of the '882 patent.

Therefore, ArthroCare failed to rebut Smith & Nephew's *prima facie* case of invalidity based on the Slager Article, and JMOL of invalidity of claims 13, 17, and 54 based on this reference is warranted. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

b. The Manwaring '138 Patent

In its cross-examination of Dr. Taylor relating to the Manwaring '138 patent (DTX 46), ArthroCare asked him about two claim limitations—"at least a portion of the energy induced is in the form of photons having a wavelength in the ultraviolet spectrum" and "evacuating fluid generated at the target site." ArthroCare also asked about these same two limitations in its cross-

¹⁵ Claim 1 of the '882 patent was reduced to practice in June 1993, and there is no evidence that the invention progressed to use in live patients in that time. Further, the language in the '592

examination of Dr. Manwaring. However, ArthroCare failed to rebut Smith & Nephew's invalidity case in either cross-examination, and did not introduce any rebuttal evidence of its own.

i. UV Photons

Dr. Taylor testified that the Manwaring '138 patent discloses UV photons. (D.I. 416 at 1316; Exhibits G and H). ArthroCare did not introduce any contrary testimony. Instead, ArthroCare attempted to mislead the jury by suggesting that, because Dr. Taylor did not test for UV photons, UV photons were not present at all. (D.I. 416 at 1429). However, as discussed above, Dr. Taylor explained why UV photons are inherently present when you have sparking in an aqueous solution, such as the sparking found in the Manwaring '138 patent, as a matter of elementary chemistry. (See D.I. 416 at 1316 and DTX 46 at col. 6, lines 50-63).

Dr. Taylor's opinion was corroborated by Dr. Manwaring. (D.I. 414 at 893-95 and 917-19). ArthroCare did not introduce any contrary testimony and Dr. Manwaring also never wavered on cross-examination. Instead, ArthroCare attempted to mislead the jury by suggesting that, because UV photons were not explicitly disclosed, UV photons were not present at all. (D.I. 414 at 897-98). But making such a suggestion does not satisfy ArthroCare's obligation to introduce evidence relating to validity. *Verdegaal Bros.*, 814 F.2d at 631; *IPPV Enterprises, LLC*, 191 F. Supp. 2d at 561-62.

Thus, ArthroCare failed to rebut the testimony of either Dr. Taylor or Dr. Manwaring regarding the inherent presence of UV photons.

ii. Evacuating Fluid Generated at the Target Site

Dr. Taylor testified that the Manwaring '138 patent discloses evacuating fluid generated at the target site. (D.I. 416 at 1316-17; Exhibits G and H). ArthroCare did not introduce any contrary testimony. Instead, ArthroCare attempted to obfuscate the issues and mislead the jury by suggesting an improper limitations to this claim.

patent, which was reduced to practice in February 1993, includes almost identical language: "method for applying energy to a target site on a body structure on or within a patient's body."

First, ArthroCare attempted to mislead the jury by suggesting that *all* of the fluid at the target site must be evacuated (D.I. 416 at 1432-33) (emphasis added):

Q. Right. But you are not going to take the fluid from this region at the tip and suck *all of the fluid way over here, way up into the device and leave no fluid down at the tip*, are you? You're going to suck fluid in, so that electrode tip has some fluid in contact with it; right?

A. Oh, yes.

ArthroCare asked similarly misleading questions of Dr. Manwaring during his cross-examination (D.I. 414 at 904-05):

Q. So isn't it fair to say, then, that [sic] fluid remains at or on the target site, that you are trying to treat in the course of a surgery?

A. That's correct.

This was clearly misleading because there is no requirement that *all of the fluid* be evacuated. (See JTX-2 at claim 54 and col. 23, lines 24-33). ArthroCare's misleading suggestion does not overcome Dr. Taylor's and Dr. Manwaring's testimony that the Manwaring '138 patent discloses evacuation.

Second, ArthroCare tried to suggest that what is evacuated is not fluid generated at the target site, but rather the electrically conducting fluid (D.I. 414 at 903-04). This suggestion is irrelevant and misleading because, as Dr. Manwaring explained, the lumen would evacuate a mixture including saline as well as fluid that was generated at the target site (D.I. 414 at 921-21):

Q. Would there be some fluid that was removed from the target site?

A. Yes. Fluid would always be there, and the evacuation, whether it is sucking, essentially pulls fluid which is salt laden, electrically conductive, by the electrode. That's the principle.

Q. Do you consider that evacuation?

A. Yes.

Q. Now, the fluid that is evacuated, would that include fluid that was generated at the target site?

A. It can.

Q. What kind of fluid would that include?

A. Well, heating in the presence of biologic tissue. Let's say one is ablating, which means removing, tumor tissue in the brain. That tissue is vaporized. And in that vaporization is fluid in the form of gas, which quickly mingles with the spinal fluid or the irrigated normal saline. So it's a mix again.

This is consistent with the explicit disclosure of the '882 patent. (JTX-2 at col. 23, lines 30-34). Thus, ArthroCare failed to rebut the testimony of either Dr. Taylor or Dr. Manwaring regarding the evacuation of fluid generated at the target site.

Therefore, ArthroCare failed to rebut Smith & Nephew's *prima facie* case of invalidity of the asserted claims based on the Manwaring '138 patent and the Court should enter JMOL that claims 13, 17, and 54 are anticipated. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

c. Enablement

Dr. Taylor also testified that the '882 patent is invalid for lack of enablement. (D.I. 416 at 1320-25). The test for whether patent claims are enabled is whether the specification teaches those of ordinary skill in the art how to make and use the full scope of the invention without undue experimentation. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988).

The specification explains that the process of the '882 results in phenomenon the inventors called "cold ablation," which "can be precisely controlled to only affect a thin layer of cells without heating or otherwise damaging surrounding or underlying cells." '882 patent at 11:38-41.

The specification itself essentially establishes the enablement problem :

The necessary conditions for forming a vapor layer near the active electrode tip(s), ionizing the atom or atoms within the vapor layer and inducing the discharge of energy from plasma within the vapor layer will depend on a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors.

Id. at 11:4-13. The specification further explains that the ionization induces the discharge of energetic electrons only "under optimal conditions." *Id.* at 10:65-66.

Despite this requirement of "optimal" conditions, the specification fails to specify what particular parameters should be used. Instead, the specification gives large ranges of parameters for nine different variables, with no guidance as to what particular combinations would result in the "optimal conditions" required for cold ablation.

Despite using this term in the patent, the evidence showed that ArthroCare itself recognized that the method of operation of its invention is not new at all, but identical to the prior art. ArthroCare has frequently backed off of this "cold ablation" assertion. Specifically, as Dr. Taylor explained, the principle of operation of the System 970, which ArthroCare asserts is covered by the patents-in-suit Tr. 1505 is the same as how prior art devices work (D.I. 416 at 1323) (emphasis added):

Q. Do you have any opinion as to whether ArthroCare's description of the mode of operation or the principle of operation of its System 970 is consistent with the opinion that you have offered here in court in this morning?

A. Yes. Essentially, the opinion that I have, I think what is confirmed here in the text, is that *the system operates in the same manner as a conventional electrosurgical system, use of arcing and such, that is described by what is known as prior art*, stuff that has been known for a long time.

With this understanding, and admission that the allegedly patented devices operate like prior art electrosurgical devices, Dr. Taylor, who was clearly qualified as one of skill in the art [cite], testified that if ArthroCare tried to distinguish its patents over the prior art based on its alleged "Coblation" phenomenon, the claims would not be enabled (D.I. 416 at 1324-25):

Q. Do you have an opinion as to whether the claims of the '882 patent are enabled to the extent it claims a new phenomenon?

A. Yes, I have an opinion.

Q. What is that opinion?

A. That it is not.

On cross-examination, Dr. Taylor did not contradict this testimony. ArthroCare's counsel merely cross-examined him on a laundry list of preferred embodiment parameters that were included in the '882 patent. (D.I. 416 at 1436-38). However, this did not rebut Dr. Taylor's testimony in any way. None of these preferred embodiment parameters discloses how one skilled

in the art duplicating the device would get a device that produces "Coblation" instead of the prior art arcing described in ArthroCare's principle of operation.

Further, if one were to build a device within the preferred embodiment parameters of the '882 patent, the result would simply be the device of the prior art Manwaring '138 patent. Here is a comparison of the most preferred embodiment of the '882 patent to the disclosure in the Manwaring '138 patent:

| <u>Preferred element</u> | <u>'882 Patent</u> | <u>The Manwaring '138 Patent</u> |
|--------------------------------------------------|----------------------------------------------------------|------------------------------------------|
| Active electrode surface area | 1 to 20 mm ² (15:37-39) | 1.4 mm ² (5:20-27) |
| Active electrode spaced from tissue | 0.05 to 0.5 mm (15:63-66) | 0 to 2 mm (5:55-61 and 6:53-57) |
| Active electrode may be flush with probe surface | (16:55-56) | (5:55-61) |
| Active electrode may be recessed from surface | 0.01 to 0.2 mm (16:57-60) | 0 to 2 mm (5:55-61) |
| Active electrode may be several materials | platinum, titanium tantalum or tungsten (16:64-66) | stainless steel or tungsten (5:20-21) |
| Fluid is preferably saline | (12:38-40) | (7:6-8) |

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case of invalidity based on non-enablement, and the Court should enter JMOL. *See generally, Enzo Biochem., Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999) (finding that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure" and that "reasonable detail must be provided in order to enable members of the public to understand and carry out the invention").

4. The '592 Patent

Smith & Nephew also proved by clear and convincing evidence that the asserted claims of the '592 patent are invalid. Specifically, Dr. Taylor provided a limitation-by-limitation analysis of how the Doss '007 patent (DTX 17; D.I. 416 at 1325-30; Exhibit I) and Slager Article (DTX 65; D.I. 416 at 1330-34; Exhibit J) each anticipate the asserted claims of the '592 patent. ArthroCare again provided no rebuttal evidence to contradict Dr. Taylor's testimony, and instead

relied on its cross-examination of Dr. Taylor to confuse and mislead the jury. However, Dr. Taylor did not withdraw or contradict his testimony during cross-examination.

a. Doss '007

In its cross-examination of Dr. Taylor relating to the Doss '007 patent (DTX 17), ArthroCare asked about only two claim limitations—"return electrode" and "voltage [] in the range from 500 to 1400 volts peak to peak." See, e.g., JTX-3, claims 1 and 21. But once again ArthroCare failed to elicit any testimony to rebut Smith & Nephew's invalidity case.

i. Return Electrode

The '592 patent contains the same "return electrode" limitation as the '536 patent, discussed above at Section 2(b)(i). And as with the '536 patent, ArthroCare did not rebut Dr. Taylor's testimony that the Doss '007 patent discloses a return electrode. Further, this limitation is found in independent claim 1. Since ArthroCare did not argue the validity of claims 3, 4, or 11 separately, their validity will stand or fall with independent claim 1. *Richardson-Vicks*, 122 F.3d at 1480.

ii. Voltage in the Range From 500 to 1400 Volts

Dr. Taylor testified that the Doss '007 patent inherently discloses a voltage in the range from 500 volts to 1400 volts peak to peak. (D.I. 416 at 1330). ArthroCare put on no evidence to rebut this testimony. Instead, ArthroCare once again limited its cross-examination to simply showing that the limitation was not expressly disclosed, ignoring the settled law that a limitation can be present in anticipating prior art inherently. *MEHL/Biophile*, 192 F.2d at 1365.

As explained by Dr. Taylor, instead of disclosing the peak to peak voltage, the Doss '007 patent discloses a voltage of 20 to 200 volts RMS (root-mean-square). To convert from voltage expressed in RMS, one needs to multiply by 2.83 to get voltage expressed in peak-to-peak units. (D.I. 416 at 1330). This conversion results in a voltage of 560 volts peak-to-peak for the Doss '007 patent. (*Id.*). ArthroCare attempted to confuse the jury regarding this inherent disclosure by

asking Dr. Taylor whether the Doss '007 patent expressly disclosed a sine wave, which is the most common waveform used. (D.I. 416 at 1402). Dr. Taylor maintained his opinion (*id.*):

Q. And there is nothing in the Doss patent that says that a sine wave is used with this generator; correct?

A. That's correct.

Q. So we don't know whether there is a sine wave here or a square wave or some other waveform; right?

A. You're correct. But, to my knowledge, there are no commercially-available square wave generators.

Thus, ArthroCare failed to rebut Dr. Taylor's testimony that the Doss '007 patent inherently discloses a voltage of from 500 to 1400 volts peak-to-peak.

Therefore, ArthroCare has not rebutted Smith & Nephew's *prima facie* case that the asserted claims of the '536 patent are invalid as anticipated by the Doss '007 patent, and JMOL based on this reference is clearly warranted. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

b. Slager Article

In its cross-examination of Dr. Taylor relating to the Slager Article (DTX 65), ArthroCare asked only about one claim limitation—"spacing a return electrode away from the body structure in the presence of the electrically conductive fluid"; and the preamble language—"applying electrical energy to a target site on a body structure on or within a patient's body." See JTX-3 at claim 23. ArthroCare again failed to elicit testimony sufficient to rebut Smith & Nephew's invalidity case. Further, this limitation is found in independent claim 23. Since ArthroCare did not argue the validity of claims 26, 27, 32, or 42 separately, their validity will stand or fall with independent claim 1. *Richardson-Vicks*, 122 F.3d at 1480

i. Applying Energy to a Target Site on a Body Structure on or Within a Patient's Body

The '592 patent contains the same "on or within a patient's body" limitation as the '882 patent. And as discussed above with respect to the '882 patent in Section F(3)(a)(iii), ArthroCare

did not rebut Dr. Taylor's testimony that the Slager Article discloses a method for applying energy to a target site on a body structure on or within a patient's body.

**ii. Spacing a Return Electrode Away from the Body Structure
in the Presence of the Electrically Conductive Fluid**

The Slager Article expressly discloses that a section of aortic tissue approximately 4 by 7 centimeters in size was used in an *in vitro* experiment. (DTX 65 at 1382.) The article also discloses that the spacing between the active electrode and return electrode varied between 2 to 10 centimeters. (*Id.* at 1383.) Thus, when the distance between the electrodes was 7 centimeters or more, the return electrode was necessarily not touching the aortic tissue sample. Dr. Taylor testified that the Slager Article discloses spacing a return electrode away from the body structure in the presence of the electrically conductive fluid. (D.I. 416 at 1331). ArthroCare did not introduce any testimony to the contrary. Instead, ArthroCare asked Dr. Taylor a series of misleading cross-examination questions regarding an experiment described in the Slager Article on which Dr. Taylor was *not* basing his testimony.

Specifically, the Slager Article describes both an *in vitro* and an *in vivo* experiment. (See DTX 65). These are two different experiments. Dr. Taylor based his opinion of invalidity on the *in vitro* experiment. His testimony on this point could not have been clearer. (D.I. 416 at 1414):

Q. And the portions of this article that you were saying were relevant to the '882 and the '592 patent related to the *in vitro* test; correct? Not to the test on the pig?

A. You said the *in vitro* test?

Q. I did.

A. Yes.

Q. Okay. The *in vitro* means what in this article?

A. *In vitro* means it's outside the body, generally in a dish preparation of some sort. I guess it's the opposite of *in vivo*, which is inside the body.

ArthroCare's counsel nevertheless went on to ask misleading questions about the irrelevant *in vivo* experiment, which did not form any part of the basis for Dr. Taylor's testimony (D.I. 416 at 1416-18). The jury may have been misled to believe that because the *in vivo*

experiment did not disclose all of the limitations, the same is true for the *in vitro* test. While the jury may have been misled, this cross examination did not rebut Dr. Taylor's clear testimony that the *in vitro* test in the Slager Article discloses a return electrode spaced away from the body structure in the presence of the electrically conductive fluid, nor does it rebut the explicit disclosure of the Slager Article. See *Ultradent Prods.*, 127 F.3d at 1068 (a reference anticipates if any one embodiment anticipates, even if other embodiments do not).

Thus, ArthroCare did not rebut Smith & Nephew's *prima facie* case that the asserted claims of the '592 patent are invalid as anticipated by the Slager Article, and JMOL is warranted based on this reference. *U.S. Environmental Prods.*, 911 F.2d at 716; *Hycor*, 740 F.2d at 1537.

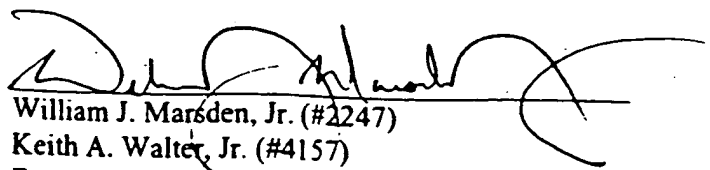
V. CONCLUSION

For the foregoing reasons, Smith & Nephew respectfully requests that the Court enter Judgment as a Matter of Law that the '882 certificate of correction is invalid, that the accused products do not infringe the asserted claims, that the asserted claims of the '536 and '592 patent are anticipated by the prior art, and that the asserted claims of the '882 patent are not enabled and are anticipated by the prior art.

Dated: June 30, 2003

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CERTIFICATE OF SERVICE

I hereby certify that on this 30TH day of June, 2003, a true and correct copy of SMITH & NEPHEW'S OPENING BRIEF IN SUPPORT OF ITS RULE 50(b) MOTION FOR JUDGMENT AS A MATTER OF LAW was caused to be served on the attorneys of record at the following addresses as indicated:

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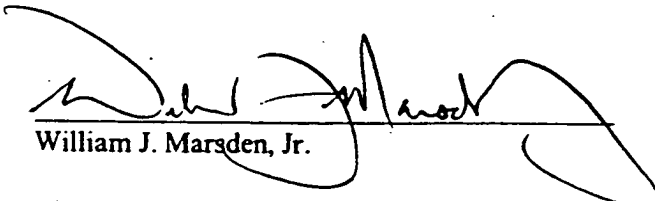
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